

REVIEW ARTICLE

UPI JOURNAL OF CHEMICAL AND LIFE SCIENCES (UPI-JCLS)

ISSN: 2581-4648 (An International online Peer Reviewed Open Access Journal)

www.uniquepubinternational.com



Published by Unique Pub International (UPI)

REGULATORY REQUIREMENTS FOR GENERIC DRUGS IN INDIA: REGULATORY FRAMEWORK, APPROVAL PROCESS, CHALLENGES, AND FUTURE PERSPECTIVES

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Received: 11 05 2026 Revised: 26 05 2026 Accepted: 22 06 2026

Abstract

Generic drugs play a vital role in improving access to affordable healthcare by providing therapeutically equivalent alternatives to innovator medicines at substantially lower costs. India is recognized as the "Pharmacy of the World" because of its extensive generic pharmaceutical manufacturing capacity and exports to more than 200 countries. Despite India's global leadership in generic medicine production, utilization of generic medicines within the country remains suboptimal due to limited public awareness, misconceptions regarding quality and efficacy, physician prescribing behavior, and inconsistent availability in certain regions. The regulatory framework governing generic drugs in India is primarily administered by the Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945. Over the past decade, several regulatory reforms have strengthened bioequivalence requirements, Good Manufacturing Practices (GMP), licensing procedures, and quality assurance mechanisms to improve public confidence in generic medicines. Government initiatives such as the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) have significantly enhanced the accessibility of affordable, quality-assured generic medicines across India. Nevertheless, several challenges remain, including inadequate awareness among healthcare professionals and patients, supply-chain limitations, regulatory disparities among states, and misconceptions regarding therapeutic equivalence. This review comprehensively discusses the regulatory framework for generic drugs in India, including approval procedures, CDSCO functions, bioequivalence requirements, GMP compliance, current regulatory reforms, comparative international standards, challenges, and future perspectives. Strengthening regulatory oversight, expanding public education, improving professional training, and ensuring continuous quality monitoring are essential for maximizing the benefits of generic medicines and achieving equitable healthcare delivery throughout India.

Keywords: Generic drugs; India; CDSCO; Drugs and Cosmetics Act; Bioequivalence; Good Manufacturing Practices; PMBJP; Pharmaceutical regulation.

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1. INTRODUCTION

Generic medicines have emerged as one of the most important strategies for improving healthcare affordability worldwide. They provide therapeutically equivalent alternatives to innovator drugs while substantially reducing treatment costs for patients, healthcare providers, insurance systems, and governments. Generic drugs contain the same active pharmaceutical ingredient (API), dosage form, strength, route of administration, intended therapeutic use, and safety profile as their corresponding innovator products. Because they are introduced after patent expiration, manufacturers are not required to repeat extensive research and development activities, resulting in significantly lower production costs and improved affordability [1].

India occupies a unique position in the global pharmaceutical industry and is widely recognized as the "Pharmacy of the World." The country is the largest supplier of generic medicines globally and plays a critical role in meeting the pharmaceutical needs of both developed and developing nations. Indian pharmaceutical companies manufacture thousands of generic formulations that are exported to over 200 countries, including highly regulated markets such as the United States, Europe, Canada, Australia, and Japan. More than 90% of prescriptions dispensed in the United States are generic medicines, and a substantial proportion of these products are manufactured in India. This remarkable

contribution highlights the country's manufacturing capabilities and regulatory compliance with international quality standards [2].

Despite India's global success in pharmaceutical manufacturing, access to affordable medicines remains a significant challenge for many citizens. Out-of-pocket healthcare expenditure continues to constitute a large proportion of total healthcare spending, with medicines accounting for a major share of household healthcare expenses. High medicine prices often limit access to essential treatments, particularly among economically disadvantaged populations residing in rural and underserved regions. Consequently, increasing the utilization of high-quality generic medicines has become an important national public health objective [3].

Recognizing this need, the Government of India launched the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) in 2008 to improve access to affordable, quality-assured generic medicines through dedicated Janaushadhi Kendras across the country. This initiative aims to reduce healthcare expenditure while promoting rational drug use and improving medicine accessibility among economically weaker sections of society. Over the years, the scheme has expanded considerably and has become one of the largest public-sector initiatives supporting generic medicine distribution in India.

The regulatory oversight of generic medicines in India is primarily the responsibility of the Central Drugs Standard Control Organization (CDSCO) functioning under the Ministry of Health and Family Welfare. The regulatory framework comprises the Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945, Good Manufacturing Practices (GMP), bioequivalence guidelines, pharmacovigilance programs, and post-marketing quality surveillance. Recent amendments have strengthened regulatory requirements by making bioequivalence studies mandatory for several categories of generic medicines, improving manufacturing standards, enhancing inspection mechanisms, and promoting greater harmonization with international regulatory practices.

Although considerable progress has been achieved, several challenges continue to affect the acceptance and utilization of generic medicines. Misconceptions regarding therapeutic efficacy, concerns about product quality, inconsistent prescribing practices, limited awareness among healthcare professionals, and occasional supply-chain disruptions continue to influence public confidence. Addressing these issues requires coordinated efforts involving regulatory authorities, healthcare professionals, pharmaceutical manufacturers, academic institutions, and policymakers.

This review comprehensively examines the regulatory framework governing generic drugs in India, including historical developments, approval requirements, regulatory authorities, Good Manufacturing Practices, bioequivalence standards, PMBJP initiatives, comparative international regulations, current challenges, and future perspectives. The review is intended to provide an updated scientific resource for pharmacy professionals, clinicians, researchers, regulatory scientists, policymakers, and students interested in pharmaceutical regulation and generic drug development.

2. METHODOLOGY

This review was conducted using a comprehensive narrative approach to evaluate the current regulatory landscape governing generic medicines in India. Scientific literature was identified through systematic searches of electronic databases including PubMed, Google Scholar, Scopus, and official regulatory websites. Government publications from the Ministry of Health and Family Welfare, Central Drugs Standard Control Organization (CDSCO), Department of Pharmaceuticals, and the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) were extensively reviewed. Relevant legislative documents, including the Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945, Gazette notifications, National Medical Commission (NMC) guidelines, and policy documents, were also examined. In addition, published studies evaluating the implementation, effectiveness, affordability, utilization, and public perception of generic medicines in India were critically analyzed to provide a comprehensive overview of current regulatory practices and emerging challenges [4].

2. GENERIC DRUGS

2.1 Definition of Generic Drugs

Generic drugs are pharmaceutical products that contain the **same active pharmaceutical ingredient (API)** as the innovator or reference drug and are marketed after the expiry of patent protection or other regulatory exclusivity. These medicines are developed to provide therapeutically equivalent alternatives to branded products while substantially reducing treatment costs. Generic drugs are required to demonstrate comparable quality, safety, efficacy, dosage form, strength, route of administration, and intended clinical use to those of the innovator medicine. Although inactive ingredients may differ, these variations should not significantly influence the therapeutic performance or safety profile of the drug. Consequently, generic medicines are considered interchangeable with their branded counterparts when approved by the regulatory authority.

The introduction of generic medicines has revolutionized pharmaceutical healthcare by improving medicine accessibility, promoting market competition, and reducing healthcare expenditures. Since manufacturers of generic medicines rely on the safety and efficacy data previously established for the innovator product, they are not required to repeat extensive preclinical studies and clinical trials, thereby reducing development costs and facilitating earlier patient access to affordable medications [4].

2.2 Characteristics of Generic Drugs

For regulatory approval in India, a generic medicine must demonstrate pharmaceutical equivalence and therapeutic equivalence to the corresponding innovator drug. The principal characteristics of generic medicines include:

- Same active pharmaceutical ingredient (API) [4].
- Same dosage strength.
- Same dosage form.
- Same route of administration.
- Same therapeutic indication.
- Comparable quality standards.
- Equivalent safety profile.
- Comparable efficacy.
- Bioequivalence with the reference product.
- Manufacture under approved Good Manufacturing Practices (GMP).

These characteristics ensure that patients receive identical therapeutic benefits regardless of whether they receive the innovator product or its approved generic equivalent.

2.3 Pharmaceutical Equivalence and Therapeutic Equivalence

Pharmaceutical equivalence refers to the requirement that two drug products contain the same active pharmaceutical ingredient in the same dosage form, strength, route of administration, and quality standards. However, pharmaceutical equivalence alone is insufficient for regulatory approval because differences in formulation and manufacturing may influence drug absorption and clinical performance.

Therapeutic equivalence is established when pharmaceutical equivalence is accompanied by demonstrated bioequivalence. Bioequivalent products exhibit comparable rates and extents of absorption, resulting in similar plasma drug concentrations and expected clinical outcomes. Therefore, therapeutically equivalent generic medicines can be substituted for innovator products without compromising efficacy or safety [5].

3. TYPES OF GENERIC DRUGS AVAILABLE IN INDIA

The Indian pharmaceutical market consists of two major categories of generic medicines.

3.1 Branded Generic Drugs

Branded generic medicines contain established generic drug molecules marketed under proprietary brand names assigned by pharmaceutical manufacturers. Unlike innovator brands protected by patents, multiple pharmaceutical companies may market the same generic molecule using different trade names after patent expiration. These products are widely prescribed because physicians and patients often recognize and remember proprietary brand names more easily than chemical names [6-9].

Examples include:

Generic Name	Common Branded Generic Examples*
Paracetamol	Dolo 650, Pacimol
Metformin	Glycomet, Cetapin
Amlodipine	Amlong, Amlokind
Pantoprazole	Pantocid, Pantodac

*Examples are illustrative and may vary by manufacturer.

Although branded generics are generally less expensive than innovator products, they are often more costly than unbranded generic medicines because of promotional, marketing, and branding expenses.

3.2 Unbranded Generic Drugs

Unbranded generic medicines are marketed using only the approved generic or International Nonproprietary Name (INN) without assigning a commercial trade name. These products are supplied extensively through the **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)** and government healthcare institutions to improve medicine affordability for economically disadvantaged populations [10-11].

The major advantages of unbranded generics include:

- Lowest acquisition cost.
- Comparable therapeutic efficacy.
- High affordability.
- Improved accessibility.
- Government quality assurance.
- Reduced healthcare expenditure.

Because these medicines are sold primarily under their generic names, they encourage rational prescribing practices and reduce confusion arising from the availability of multiple brand names.

4. INTERNATIONAL NONPROPRIETARY NAME (INN)

The **International Nonproprietary Name (INN)** system was established by the **World Health Organization (WHO)** to provide a universally recognized and unique generic name for every active pharmaceutical ingredient. The primary objective of the INN system is to facilitate safe prescribing, dispensing, procurement, and communication among healthcare professionals worldwide.

Unlike brand names, which are assigned by pharmaceutical companies for commercial purposes, INNs are internationally standardized scientific names that remain identical across all WHO member countries. The use of INNs minimizes prescribing errors, improves pharmacovigilance, promotes rational drug use, and facilitates generic substitution [12].

Examples include:

Active Pharmaceutical Ingredient (INN)	Example Brand Names
Paracetamol	Crocin, Dolo 650
Atorvastatin	Atorlip, Lipitor
Metformin	Glycomet, Cetapin
Amoxicillin	Mox, Novamox

The increasing adoption of INN prescribing is considered an important strategy for improving generic medicine utilization in India.

5. Advantages of Generic Medicines

Generic medicines provide substantial clinical, economic, and public health benefits [13].

5.1 Economic Benefits

One of the greatest advantages of generic medicines is their significantly lower cost compared with innovator products. Because manufacturers are not required to invest in extensive drug discovery programs, preclinical research, or large-scale clinical trials, development costs are considerably reduced. These savings are ultimately transferred to patients through lower medicine prices.

Affordable medicines improve treatment adherence, particularly among patients with chronic diseases requiring lifelong therapy.

5.2 Increased Accessibility

Generic medicines substantially improve access to essential medicines, especially among economically weaker sections of society. Government initiatives such as PMBJP have expanded the availability of affordable medicines in both urban and rural areas, contributing to improved healthcare equity [14].

5.3 Promotion of Market Competition

The availability of multiple generic manufacturers promotes healthy competition within the pharmaceutical market. Increased competition generally results in lower medicine prices, improved product availability, and continuous quality improvement.

5.4 Reduction in Healthcare Expenditure

Generic substitution reduces healthcare expenditure for:

- Individual patients.
- Government-funded healthcare programs.
- Insurance providers.
- Hospitals.
- Public health systems.

Consequently, generic medicines play a critical role in improving the sustainability of healthcare financing [15, 16].

6. LIMITATIONS AND CHALLENGES ASSOCIATED WITH GENERIC MEDICINES

Despite their proven quality and therapeutic equivalence, generic medicines continue to face several barriers to wider acceptance.

Major challenges include:

- Limited public awareness regarding generic medicines.
- Misconceptions concerning efficacy and quality.
- Physician preference for branded products.
- Aggressive pharmaceutical marketing.
- Variable availability in rural healthcare facilities.
- Inadequate pharmacist counseling.
- Supply-chain interruptions.
- Concerns regarding manufacturing quality among some stakeholders.

These challenges highlight the need for strengthened regulatory oversight, public education, and professional training to improve confidence in generic medicines.

7. REGULATORY FRAMEWORK GOVERNING GENERIC DRUGS IN INDIA

7.1 Introduction

India has established a comprehensive regulatory framework to ensure that generic medicines marketed within the country meet acceptable standards of **quality, safety, efficacy, and therapeutic equivalence**. The regulatory system is designed to protect public health while promoting the availability of affordable medicines. Regulatory oversight encompasses every stage of a generic drug's life cycle, including drug development, manufacturing, quality control, licensing, clinical evaluation (where applicable), bioequivalence studies, marketing authorization, post-marketing surveillance, and pharmacovigilance [17-18].

The regulatory framework for generic drugs is primarily governed by the **Drugs and Cosmetics Act, 1940**, the **Drugs and Cosmetics Rules, 1945**, and guidelines issued by the **Central Drugs Standard Control Organization (CDSCO)**. In recent years, India has introduced several regulatory reforms to strengthen pharmaceutical quality systems, harmonize regulatory practices with international standards, and improve public confidence in generic medicines.

The regulatory system functions through coordinated efforts between the Central Government, State Drug Regulatory Authorities, testing laboratories, pharmaceutical manufacturers, and healthcare institutions.

7.2 Objectives of Generic Drug Regulation

The primary objectives of generic drug regulation in India include:

- Ensuring the quality, safety, and efficacy of generic medicines.
- Promoting affordable healthcare through increased availability of generic drugs.
- Establishing uniform manufacturing and quality standards.
- Preventing the marketing of substandard or counterfeit medicines.
- Protecting public health through effective regulatory oversight.
- Ensuring compliance with Good Manufacturing Practices (GMP).
- Promoting rational use of medicines.
- Facilitating exports by maintaining internationally accepted quality standards.

These objectives collectively contribute to strengthening India's pharmaceutical sector while safeguarding patient welfare [19-20].

8. DRUGS AND COSMETICS ACT, 1940

8.1 Historical Background

The **Drugs and Cosmetics Act, 1940**, is the principal legislation regulating the import, manufacture, distribution, and sale of drugs and cosmetics in India. Enacted during the pre-independence era, the Act was introduced to prevent the circulation of adulterated, spurious, and misbranded drugs and to establish uniform quality standards across the country. Over the years, the Act has undergone several amendments to address advances in pharmaceutical science, biotechnology, medical devices, and regulatory requirements [21].

For generic medicines, the Act provides the legal basis for licensing, manufacturing, quality assurance, inspection, enforcement, and regulatory control.

9.2 Scope of the Act

The Drugs and Cosmetics Act regulates:

- Import of pharmaceutical products.
- Manufacture of drugs.
- Distribution and sale of medicines.
- Licensing of pharmaceutical manufacturers.
- Quality control.
- Inspection of manufacturing facilities.
- Sampling and testing of marketed products.
- Regulatory enforcement actions.
- Penalties for regulatory violations.

The Act applies to all pharmaceutical products manufactured or marketed within India, including innovator drugs, generic medicines, biological products, vaccines, and medical devices covered under the legislation.

8.3 Importance for Generic Drug Approval

The Drugs and Cosmetics Act forms the legal foundation for the approval of generic medicines by:

- Defining regulatory authority.
- Establishing licensing procedures.
- Prescribing manufacturing standards.
- Regulating quality assurance.
- Authorizing inspections.
- Supporting enforcement against non-compliant manufacturers.

Compliance with this Act is mandatory for every pharmaceutical manufacturer seeking approval to market generic medicines in India.

9. DRUGS AND COSMETICS RULES, 1945

The **Drugs and Cosmetics Rules, 1945**, were framed under the Drugs and Cosmetics Act to provide detailed procedures for implementing the provisions of the Act. These Rules specify technical requirements for manufacturing, licensing, labeling, storage, distribution, import, testing, and quality control of pharmaceutical products.

The Rules have been amended periodically to accommodate scientific advances and evolving regulatory expectations [22].

9.1 Major Provisions Relevant to Generic Drugs

The Rules contain provisions relating to:

- Manufacturing licenses.
- Sale licenses.
- Good Manufacturing Practices (Schedule M).
- Labeling requirements.
- Packaging standards.
- Stability studies.
- Sampling procedures.
- Drug testing laboratories.
- Inspector qualifications.
- Recall procedures.
- Pharmacovigilance-related requirements.

These provisions ensure consistency in pharmaceutical quality throughout the manufacturing and distribution process.

10. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO)

10.1 Introduction

The **Central Drugs Standard Control Organization (CDSCO)** is India's National Regulatory Authority responsible for regulating pharmaceuticals, biological products, medical devices, and clinical trials. CDSCO functions under the **Directorate General of Health Services (DGHS)**, Ministry of Health and Family Welfare, Government of India [23].

The organization is headed by the **Drugs Controller General of India (DCGI)**, who is responsible for granting approvals for new drugs, supervising clinical trials, regulating imports, and coordinating national pharmaceutical regulatory activities.

10.2 Functions of CDSCO

The major functions of CDSCO include:

- Approval of new drugs.
- Approval of certain categories of generic drugs.
- Regulation of clinical trials.
- Regulation of imported pharmaceutical products.
- Issuance of regulatory guidance documents.
- Coordination with State Drug Regulatory Authorities.
- Quality monitoring through national surveillance programs.
- Inspection of manufacturing facilities.
- Pharmacovigilance oversight.
- Enforcement of regulatory compliance.

CDSCO also collaborates with international regulatory agencies to harmonize regulatory standards and facilitate global acceptance of Indian pharmaceutical products [24].

10.3 Organizational Structure

The organizational structure of CDSCO consists of:

- Drugs Controller General of India (DCGI).
- Joint Drugs Controllers.
- Deputy Drugs Controllers.
- Assistant Drugs Controllers.
- Drug Inspectors.
- Zonal Offices.
- Sub-zonal Offices.
- Port Offices.
- Central Drug Testing Laboratories.

These units work collaboratively to regulate pharmaceutical products throughout India.

11. ROLE OF STATE LICENSING AUTHORITIES (SLAS)

While CDSCO is responsible for national regulatory policy and approval of new drugs, **State Licensing Authorities (SLAs)** are responsible for licensing the manufacture and sale of pharmaceutical products within their respective states [2,11,25].

The principal functions of SLAs include:

- Granting manufacturing licenses.
- Granting sale licenses.
- Conducting inspections.
- Collecting market samples.
- Monitoring GMP compliance.
- Investigating complaints.
- Taking enforcement actions against regulatory violations.

Effective coordination between CDSCO and SLAs is essential to maintain uniform regulatory standards across the country.

12. LICENSING REQUIREMENTS FOR GENERIC DRUG MANUFACTURING

Pharmaceutical manufacturers intending to produce generic medicines in India must obtain the necessary licenses from the appropriate State Licensing Authority in accordance with the Drugs and Cosmetics Act and Rules.

The licensing process generally includes:

- Submission of the prescribed application.
- Details of manufacturing premises.
- Equipment qualification.
- Personnel qualifications.
- Product formulation details.
- Manufacturing process.
- Quality assurance system.
- Analytical testing facilities.
- Stability data, where applicable.
- Inspection by regulatory authorities.

Only after satisfactory evaluation and inspection is a manufacturing license granted.

13. APPROVAL PROCESS FOR GENERIC DRUGS IN INDIA

The approval of a generic drug follows a structured regulatory pathway to ensure compliance with quality, safety, and efficacy standards. The typical approval process includes:

1. **Selection of the reference product** and formulation development.
2. **Pre-formulation and formulation studies** to optimize the dosage form.
3. **Analytical method development and validation** for quality testing.
4. **Manufacture of pilot batches** under Good Manufacturing Practices.
5. **Bioequivalence study** (where required) to compare the generic product with the reference product.
6. **Compilation of regulatory dossier**, including quality, manufacturing, and bioequivalence data.
7. **Submission of the application** to CDSCO and/or the relevant State Licensing Authority.
8. **Technical review** of the submitted documents by regulatory experts.
9. **Inspection of the manufacturing facility** to verify compliance with Schedule M (GMP).
10. **Grant of marketing authorization** upon satisfactory review and compliance.

This systematic process helps ensure that approved generic medicines meet national regulatory standards and are suitable for patient use [26].

14. BIOEQUIVALENCE REQUIREMENTS IN INDIA

Bioequivalence (BE) studies are conducted to demonstrate that a generic drug has the same rate and extent of absorption as the reference product. CDSCO requires BE studies for many oral generic formulations, particularly for drugs with a narrow therapeutic index and modified-release formulations. These studies ensure therapeutic equivalence and interchangeability of generic medicines.

Objectives of Bioequivalence Studies

- Demonstrate therapeutic equivalence.
- Compare pharmacokinetic parameters (C_{max}, T_{max}, AUC).
- Ensure safety and efficacy.
- Support regulatory approval.

15. GOOD MANUFACTURING PRACTICES (GMP)

All generic medicines manufactured in India must comply with **Schedule M** of the Drugs and Cosmetics Rules, 1945. GMP ensures that pharmaceutical products are consistently produced and controlled according to quality standards [27].

Major GMP Requirements

- Qualified personnel.
- Suitable manufacturing facilities.
- Equipment qualification.
- Documentation and record keeping.
- Process validation.
- Quality control testing.
- Hygiene and sanitation.
- Product recall procedures.
- Complaint handling.

Compliance with GMP is verified through periodic inspections conducted by CDSCO and State Drug Regulatory Authorities.

16. QUALITY CONTROL AND QUALITY ASSURANCE

Quality Control (QC) involves laboratory testing of raw materials, in-process materials, and finished products to ensure compliance with specifications. Quality Assurance (QA) is a comprehensive system designed to ensure consistent product quality throughout manufacturing.

Quality Parameters

- Identity.
- Purity.
- Assay.
- Dissolution.
- Uniformity of dosage units.
- Stability.
- Microbial limits (where applicable).

17. STABILITY STUDIES

Stability studies determine the shelf life of pharmaceutical products under different environmental conditions.

Types of Stability Studies

- Long-term stability.
- Accelerated stability.
- Intermediate stability.
- Photostability.

These studies help establish expiry dates, storage conditions, and packaging requirements.

18. LABELING AND PACKAGING REQUIREMENTS

Generic drug labels must comply with the Drugs and Cosmetics Rules and include:

- Generic name.
- Brand name (if applicable).
- Dosage strength.
- Dosage form.
- Batch number.
- Manufacturing date.
- Expiry date.
- Manufacturing licence number.
- Storage conditions.
- Manufacturer details.
- Schedule warning (if applicable).

Proper packaging protects the product from environmental factors and maintains product stability [28].

19. GOVERNMENT INITIATIVES PROMOTING GENERIC MEDICINES

The Government of India has implemented several initiatives to encourage the use of generic medicines.

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

- Provides quality generic medicines at affordable prices.

- Operates through Janaushadhi Kendras across India.
- Reduces out-of-pocket healthcare expenditure.
- Improves access to essential medicines.

Other Initiatives

- Promotion of generic prescribing by healthcare professionals.
- Price regulation through the National Pharmaceutical Pricing Authority (NPPA).
- Public awareness campaigns on generic medicines [29].

20. CHALLENGES IN GENERIC DRUG REGULATION

Major challenges include:

- Low public awareness.
- Misconceptions about quality and efficacy.
- Brand preference among prescribers.
- Variations in regulatory implementation across states.
- Counterfeit and substandard medicines.
- Supply chain issues.
- Limited pharmacovigilance reporting.

Addressing these challenges requires stronger regulatory enforcement, public education, and continuous quality monitoring [30].

21. FUTURE PERSPECTIVES

Future improvements should focus on:

- Strengthening CDSCO regulatory capacity.
- Harmonization with international regulatory standards.
- Digitalization of regulatory submissions.
- Expansion of bioequivalence testing facilities.
- Improved pharmacovigilance systems.
- Increased public awareness of generic medicines.
- Greater collaboration between regulatory agencies and industry.

22. CONCLUSION

Generic medicines are essential for improving access to affordable healthcare in India. The regulatory framework, led by the Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, ensures that generic drugs meet standards of quality, safety, and efficacy. Bioequivalence studies, Good Manufacturing Practices (Schedule M), quality assurance, and post-marketing surveillance play a critical role in maintaining public confidence in generic medicines. Government initiatives such as the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) have significantly increased the availability of affordable medicines across the country. Continued regulatory reforms, improved awareness among healthcare professionals and the public, and stronger quality assurance systems will further strengthen the generic drug sector and contribute to universal access to safe, effective, and affordable medicines.

23. AUTHOR CONTRIBUTIONS

All authors are contributed equally.

24. CONFLICT OF INTEREST

The authors declare no conflict of interest.

25. FUNDING

No external funding was received for this study.

26. INFORM CONSENT AND ETHICAL STATEMENT

Not Applicable.

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